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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,865	12/27/2006	Mario Pinza	292919US0PCT	8132

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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.  
1940 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER
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DAVIS, BRIAN J

ART UNIT	PAPER NUMBER
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1621

NOTIFICATION DATE	DELIVERY MODE
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04/23/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/586,865	<b>Applicant(s)</b> PINZA ET AL.	
	<b>Examiner</b> Brian J. Davis	<b>Art Unit</b> 1621	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☒ Claim(s) 6 and 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/18/06</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The lined-through references have not been provided.

### ***Claim Objections***

Claims 6 and 11 are objected to because of the following informalities: for grammatical reasons, the definite article “the,” which appears before the term *ibopamine maleate* salt in line 1 of claim 6 and before the term *acetone* in line 2 of claim 11, should be deleted. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the limitation “ibopamine.” However there is insufficient antecedent basis for this limitation in the claim; the claim from which claims 4 and 5 depend, claim 2, recites ibopamine maleate. That is, it is unclear if claims 4 and 5 are actually intended to refer to the base (*not* recited in claim 2), or to the salt (recited in claim 2).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2,400,038 in view of US 4,764,530.

Applicant claims ibopamine maleate, an ophthalmic composition containing this salt and a method of making the salt (independent claims 1, 2 and 6).

US 2,400,038 teaches a small Markush group of compounds (see formula IIIb page 2, column 1, line 50) - which encompasses ibopamine base - and their salts (page 2, column 2, line 3). The reference explicitly teaches maleic acid salts of the compounds of formula IIIb. (The examiner notes for clarity of the record that this reference uses a simple, six-sided polygon to represent diagramed phenyl - rather than the modern notation which also includes an inscribed circle within the polygon.)

US 4,764,530 teaches pharmaceutical compositions containing ibopamine or its pharmaceutically acceptable salts for use in ophthalmological applications because of its considerable mydriatic effect (column 1, line 8). Concentrations range from 0.01-10% (w/v), preferably 0.1-5% (column 3, line 41).

First, with specific respect to US 2,400,038, the examiner notes that where a reference describes a sufficiently limited genus of a number of closely related compounds, the reference may be said to provide a description of those compounds just as if they were identified in the reference by name. *In re Schaumann*, 572 F2d. 312, 197 USPQ 5 (CCPA 1978); *In re Petering*, 301 F2d. 676, 133 USPQ 275 (CCPA 1962) (a vast number of permutations of substituent groups under a general formula was reduced to twenty compounds by recourse to “preferences” disclosed in the reference). The examiner further notes that it is well established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends

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to the entire disclosure for what it fairly teaches to a person of ordinary skill in the art. *In re Boe*, 355 F2d 961, 148 USPQ 507, 510 (CCPA 1966); *In re Chapman*, 357 F2d 418, 148 USPQ 711 (CCPA 1966); *In re Meinhardt*, 392 F2d 273, 157 USPQ 270, 272 (CCPA 1968); *In re Lamberti*, 545 F2d 747, 750, 192 USPQ 279, 280 (CCPA 1976); *In re Fracalossi*, 681 F2d 792, 794, 215 USPQ 569, 570 (CCPA 1982); *In re Kaslow*, 707 F2d 1366, 1374, 217 USPQ 1089, 1095 (Fed. Cir. 1983). Therefore, US 2,400,038 fairly and explicitly teaches ibopamine maleate salt.

US 2,400,038 also teaches that the maleic acid salt of the compounds of formula IIIb, as well as the other explicitly named salts, may be made "by the usual methods" (page 2, column 2, line 6). That is, one of ordinary skill in the art - even approximately 70 years ago - would have been intimately familiar with methods of making acid addition salts of amines. So much so that such methods did not even need to be explicitly detailed. One of ordinary skill in the art, then and now, would understand that a "usual method" would certainly include: dissolution of the free base, or one of its soluble salts, in a suitable solvent followed by the addition of the acid of the desired salt followed by routine workup (precipitation, filtration, etc.). That is, claims 6-11 merely represent a specific optimized instance of a very old and routine laboratory procedure in the chemical arts.

US 4,764,530, a general reference, teaches, as stated above, pharmaceutical compositions containing ibopamine or its pharmaceutically acceptable salts (of which a maleic acid salt is one) for use in ophthalmological applications for its considerable mydriatic effect (column 1, line 8). That is, US 4,764,530 generically teaches

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applicant's composition. Dependent claims 3-5 are included in this rejection as they represent mere optimizations of efficacious formulations and concentrations, both of which are routinely arrived at by routine laboratory experimentation.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 571-272-0638. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached at 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J. Davis/

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Primary Examiner, Art Unit 1621  
4/19/09